METHOD AND DEVICE FOR TREATING AORTIC DISSECTION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority of provisional application Ser. No. 60/430,825, filed Dec. 4, 2002.

TECHNICAL FIELD

This invention relates to a method and a device for the treatment of aortic arch disease and more particularly to the treatment of a form of aortic aneurysm known as an aortic dissection.

BACKGROUND OF THE INVENTION

An aortic dissection is a form of aneurysm to the descending aorta in which the wall of the aorta is damaged to such an extent that blood under pressure can get between inner and outer layers of the wall of the aorta to expand part of the wall into an inflated sac of blood which is referred to as a false lumen. The inflated sac of blood or false lumen so formed may extend some distance down the descending aorta and open out into the aorta again further down.

It is the object of this invention to provide a device and a method of treatment of such an aortic dissection.

Throughout this specification the term proximal with respect to both human or animal vasculature and the deployment device and prosthesis will be used to refer to the region closest to the heart or that part of the deployment device or of the prosthesis which when in use is closest to the heart and the term distal will be used for regions of the human or animal vasculature further from the heart and those parts of the deployment device or prosthesis which in use are further from the heart.

SUMMARY OF THE INVENTION

In one form therefore the invention is said to reside in a prosthesis adapted for inter-luminal placement by endovascular deployment, the prosthesis comprising a plurality of self expanding stents together defining an elongate substantially cylindrical lumen wall engaging surface and at least one of the stents having a bio-compatible graft material cover whereby the cover is adapted to close off a rupture in the wall of the lumen and the stents are adapted to provide pressure on the wall of the lumen adjacent to and extending away from the rupture.

Preferably the cover portion encompasses two or three stents and the cover is stitched or otherwise fastened to the stents in the covered portion.

Preferably the covered portion of the prosthesis is at the proximal end of the plurality of stents.

The uncovered other stents preferably extend away from the covered portion and may be linked by suitable flexible links. Alternatively the uncovered stents may be linked by a thread or fibre such as a suture threaded through the bends of the zig-zag stents. The thread or fibre such as a suture may be connected to each bend by a knot such as for example, a half hitch, a thumb knot, two half hitches, a clove hitch or a similar knot.

The proximal end of the covered portion of the prosthesis may include barbs extending from the stents through the cover to engage with the wall of the lumen when deployed.

In one preferred embodiment of the invention there may be three covered stents each of the zig-zag type and constructed from stainless steel or nitinol and up to eight or ten uncovered stents formed from stainless steel or nitinol.

The uncovered stents may be of the Gianturco type zigzag stent and constructed so that in their expanded state they provide a low but useful radial force on the aorta wall.

Alternatively the uncovered portion may be in the form of a self expanding spiral of zig-zag configuration.

In a further form the invention may be said to reside in a prosthesis for treatment of an aortic dissection comprising a substantially cylindrical body in the expanded state having at least one self expanding stent covered by a bio-compatible graft material and a self expanding stent assembly extending from a distal end thereof.

There may be included barbs extending from the proximal end of the graft.

In one embodiment the self expanding stent assembly extending from a distal end of the biocompatible graft material may be formed from a biocompatible and biodegradable mesh material so that after it has performed its work of providing a radial pressure onto the wall of the aorta it can biodegrade in the bloodstream.

The stents in these embodiments of the invention may be made MRI (Magnetic Resonance Imaging) compatible.

In one form the stent may be in the form of a Gianturco style zig zag Z stent. Alternatively the stent may be a Nitinol™ self expanding stent of the type known as a Zilver™ stent sold by Cook Incorporated.

The bio-compatible graft material may be either on the inside or the outside of the covered portion of the prosthesis.

In a further form the invention may be said to reside in a deployment device and prosthesis for treatment of an aortic dissection, the prosthesis comprising a substantially cylindrical body in the expanded state having at least one self expanding stent covered by a bio-compatible graft material and a self expanding stent assembly extending from a distal end thereof, and the deployment device comprising an elongate catheter adapted to be deployed over a guide wire, a nose cone at the proximal end of the elongate catheter, a trigger wire arrangement adapted to retain a proximal end of the prosthesis in a retracted state, a sheath arrangement over the elongate catheter adapted to retain the prosthesis in a contracted state around the elongate catheter, means at the distal end of the elongate catheter to release the trigger wire arrangement and means to withdraw the sheath arrangement.

Preferably the elongate catheter includes means to supply an angiographic contrast medium at a distal end thereof through the catheter and the nose cone includes discharge ports for the angiographic contrast medium.

In an alternative form the invention is said to reside in a method of treatment of aortic dissection disease comprising the steps of loading a prosthesis onto a deployment device, the prosthesis comprising a plurality of self expanding stents together defining an elongate substantially cylindrical lumen wall engaging surface and at least one of the stents having a bio-compatible graft material cover whereby the cover is adapted to close off a rupture in the wall of the lumen, the deployment device including means to retain the proximal end of the prosthesis in a retracted state and a trigger wire arrangement to release the proximal end of the prosthesis, a sheath to retain the entire prosthesis in a retracted state and means to withdraw the sheath, endovascularly deploying the deployment device with the prosthesis loaded thereon to the site of the aortic dissection, checking by radiographic techniques that the covered stent or stents are at the site of the aortic dissection, withdrawing the sheath to expose the cov-